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Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Spinosad for the Moscamed Program

Environmental Analysis
December 2001

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I. Need for the Proposed Action

The Mediterranean fruit fly or Medfly, *Ceratitis capitata* (Wiedemann), is one of the world's most destructive agricultural pests. A pest of over 200 fruit and vegetable crops, the Medfly is found in Europe, Asia, South America, Central America, Australia, and Hawaii. Because of its destructive potential, there have been major and costly efforts to eradicate the pest each time it was introduced into the United States, beginning in 1929. The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is cooperating with the Governments of Guatemala and Mexico in a program to eradicate the Medfly.

The Medfly was introduced into Central America in 1955 and spread by the mid-1970's to Mexico. Through a cooperative program (the Moscamed Program), the United States, Mexico, and Guatemala eradicated Medfly from Mexico in 1982. Following Medfly eradication in Mexico, APHIS, the Government of Mexico, and the Government of Guatemala jointly proposed and implemented the Guatemala Moscamed Program to eradicate the Medfly from Guatemala. For that program, APHIS prepared an environmental analysis (EA), the "Guatemala MOSCAMED Program, Environmental Analysis—1991." It comprehensively analyzed alternative program strategies and controls, unique characteristics of the Guatemalan environment, potential environmental consequences, required mitigation of environmental impacts, and applicable environmental law.

On December 7, 1993, the Assistant Secretaries of Agriculture of the United States, Mexico, and Guatemala accepted the EA as "the official and guiding environmental document for operations in Guatemala." That document remains the principal EA for the Guatemala Moscamed Program, and is incorporated by reference in this document. A second analysis, the "Guatemala MOSCAMED Program Summary Environmental Analysis, January 1996," was replaced by a third analysis, "Guatemala MOSCAMED Program, Environmental Analysis, December 1996," prepared to accommodate changes in program operations and the addition of the use of the chemical Suredye®.

The operational effectiveness and interim objectives of the Moscamed program have been influenced greatly by available resources, political change, and environmental issues. It was not possible to maintain the original eradication objective subsequent to 1991, and over the years the program adopted a strategy that minimized, to the extent possible, the damage and spread of the Medfly in Guatemala. Small, isolated outbreaks that occurred in Mexico were eradicated in the interim. Recently there have been major improvements in control technology that have been subjected to methods development research in Guatemala and

Mexico. This document specifically analyzes the potential environmental impacts of the addition of one of those developments (the control chemical spinosad) to the program. Spinosad bait also has been analyzed comprehensively in chemical risk assessments for human health (USDA, 1999a) and nontarget species (USDA, 1999b), and in the "Fruit Fly Cooperative Control Program Final Environment Impact Statement—2001" (USDA, 2001b).

This EA, like its predecessors, has been prepared in compliance with Executive Order 12114, "Environmental Effects Abroad of Major Federal Actions." APHIS' authority to cooperate in international pest control programs is based upon provisions of the Plant Protection Act (Public Law 106–224, 114 Stat. 438–455), which authorizes the Secretary of Agriculture to take measures to prevent the dissemination of a plant pest that is new to or not known to be widely prevalent or distributed within and throughout the United States.

II. Alternatives

This environmental analysis incorporates, by reference, all of the information contained within the previous APHIS Moscamed analyses, but focuses on the analysis and summarization of the potential environmental effects of newly added technology. The proposed program activities in Guatemala will continue the same basic strategy (eradication of Medfly from Guatemala using integrated control) described and analyzed in detail in the original 1991 EA, and endorsed by the Assistant Secretaries of Agriculture of the United States, Mexico, and Guatemala. As part of the eradication program in Guatemala, a flexible internal barrier will be established. That barrier, which may be relocated, depending upon the pest situation, will facilitate the eradication of Medfly in Guatemala while serving to reduce Medfly spread to Mexico. The integrated control alternative chosen by the program offers the combination of maximum environmental protection with program efficacy. The integrated control strategy selected by the Moscamed Program uses singly or in combination any of the following component control methods: sterile insect technique (SIT), chemical control, cultural control, and regulatory control.

III. Environmental Consequences

APHIS and the Moscamed Program are proposing to add the pesticide spinosad to the control methods used under the integrated control strategy. All other control methods have been comprehensively analyzed in the earlier environmental

documents, cited in section 1. The results and conclusions of those documents are incorporated by reference in this analysis, and are summarized in this section.

A. Effects in General

Moscamed's integrated control of the Medfly offers the combination of maximum environmental protection with program efficacy. Integrated control in this program uses singly, or in combination, any of the following component control methods: sterile insect technique (SIT), cultural control, regulatory control, and chemical control. The control methods that historically have posed the most direct environmental impact are the chemical control methods. The specific methods used by program officials for individual sites will vary, and mitigative procedures may be applied to limit or prevent adverse impacts at specific locations.

The use of SIT in control of Medfly populations is effective at decreasing populations of Medfly and posing minimal environmental effects. The release of sterile adult flies poses no risk to wildlife or environmental quality other than from the minimal emissions of hydrocarbons from the vehicular transport of sterile flies. The sterile flies are a potential source of food to some wildlife and the method has been determined to be compatible with protection efforts for endangered and threatened species. The testing of a genetically-sexed, temperature-sensitive lethal (TSL) strain of sterile Medflies has demonstrated more effective control, no environmental risk, and reduced need for chemical pesticide applications (Hendrichs *et al.*, 1995). These strains will be used in the current program.

Program cultural control may assist eradication efforts by lowering local Medfly populations, but is of limited effectiveness when used exclusively. Practices such as clean culture, special timing, trap crops, and resistant varieties can decrease Medfly activity with minimal environmental effects, but limited effectiveness and logistical issues make these methods of limited value, particularly for area-wide eradication programs.

Regulatory control methods are a critical part of the program, in that, they reduce the likelihood of transporting Medfly to Medfly-free areas. Quarantines and fruit destruction have minimal impact on the environment. The quarantine treatments of vehicles and agricultural commodities have specific uses in elimination of pest risk in Medfly programs. Consequences of these treatments are confined to the commodity treated. Depending upon the location of program activity, the quarantine treatments are under the regulatory authority of either the Government of Guatemala or the Government of Mexico.

The primary environmental consequences from program actions occur from the chemical treatments to eradicate Medfly. Contemporary Moscamed programs involve the ground and aerial applications of bait spray. These applications have been subject to considerable research and development in recent years. The program in Mexico is presently using malathion bait applications in their eradication programs, but steps are being taken by Mexican authorities to register a formulation of spinosad. As mentioned in the chapter on the need for the proposed program, the previous environmental documents for Moscamed programs, incorporated by reference into this environmental analysis, have assessed the environmental consequences of most application methods. The reader should refer to these documents for further information. This EA is designed specifically to present the environmental consequences from potential program use of spinosad bait spray applications in the Moscamed program in Guatemala and Mexico.

B. Added Use of Spinosad

Certain formulations of spinosad bait spray have been developed for application in Medfly eradication programs. A number of different formulations of spinosad could be used for program applications. Spinosad bait spray is registered for use in a number of Latin American countries, including Guatemala. Additional registrations are being sought in both Mexico and the United States. This analysis focuses on the consequences of this new use pattern. The actual program application rate and frequency of applications are still under development and have not yet been clearly defined. Therefore, the existing risk assessments for spinosad bait spray will not accurately reflect all site-specific impacts from the program actions under consideration. The spinosad bait spray risk assessments analyzed an application rate of 0.0003 kilogram of active ingredient per hectare (kg a.i./ha). The current program has proposed application rates for spinosad bait spray that range from 0.00019 to 0.00038 kg a.i./ha, depending upon location and test results. The treatment interval can range from 2 to 11 days depending upon the Medfly population, weather conditions, and local environmental conditions. The environmental consequences of spinosad application at the maximum allowed rate and most frequent application interval are compared in this analysis to program application rates of malathion bait to describe the relative impact of each method.

C. Overall Risks from Spinosad Bait Spray Applications

Spinosad is isolated from a naturally occurring Actinomycetes species, *Saccharopolyspora spinosa*. This insecticide contains a mixture of two

structurally similar molecules which are both active against insects and which have been designated spinosyn A and spinosyn D. Spinosad typically contains spinosyns A and D in a ratio of about 85% A to 15% D.

Spinosad was granted conditional registration based upon determination by the Environmental Protection Agency (EPA) that spinosad is a reduced risk product (U.S. EPA, 1997). This determination of reduced risk was also confirmed by the risk assessments of spinosad bait applications prepared for human health (USDA, 1999a) and nontarget species (USDA, 1999b). Results of those risk assessments of spinosad are incorporated by reference into this EA and are summarized in the next paragraphs. Unlike malathion, which is toxic by most routes (ingestion, inhalation, dermal), the route of intoxication of spinosad occurs primarily through ingestion (especially when used as a bait formulation with an extremely low percentage of active ingredient.) In insects, the spinosad mode of action results in the excitation of the system, leading to involuntary muscle contractions, prostration with tremors, and finally paralysis. These effects are consistent with the activation of nicotinic acetylcholine receptors by a mechanism that is novel and unique among known insecticide products (Salgado *et al.*, 1997). Spinosad also has effects on the gamma-amino-butyric acid (GABA) receptor function that may contribute further to its insecticidal activity and selectivity. This prolonged response leads to involuntary muscle contractions and tremors. The reason for the extraordinary margin of selectivity toward certain insects over mammals and other nontarget organisms is not fully understood.

Based upon actual environmental monitoring data collected over the past 2 years (USDA, 2000; USDA, 2001a), spinosad is not expected to have any persistent effects on the physical environment. Spinosad is not volatile and does not persist in the atmosphere. Spinosad residues may remain detectable on plants and soil for up to a week, but exposure to sunlight and moderate to heavy precipitation is expected to decrease persistence in the program areas. Spinosad is not expected to leach to groundwater due to its rapid degradation, its binding to soil organic matter, and the low program application rates. Any direct application of spinosad to water would result in low concentrations resulting from the low application rates. Photodegradation of spinosad in surface waters would result in undetectable levels within a day.

The acute toxicity of spinosad to humans and terrestrial vertebrates, such as mammals and birds, is low by all routes of exposure due to slow metabolism of the compound, low intrinsic toxicity, rapid excretion, and lack of sensitive nervous system receptors in vertebrates. None of the exposure scenarios for program personnel or the general public from applications of spinosad bait spray pose any

risks of concern. Phytotoxicity to plants and toxicity to reptiles and amphibians are not expected at the low applications rates for the program. Program aerial applications could disturb some of these organisms by the aircraft noise, but these effects are momentary and are not expected to permanently affect any vertebrate species.

Toxicity to terrestrial invertebrates from exposure to spinosad occurs primarily through ingestion, but some effects from contact exposure are possible. The limited routes of intoxication of spinosad result in less adverse effects to nontarget invertebrates than malathion. Spinosad is most toxic to caterpillars (Lepidoptera) and all stages of flies (Diptera)(Adan *et al.*, 1996). The mode of toxic action of spinosad against insects has been shown to relate to the widespread excitation of isolated neurons in the central nervous system (Salgado *et al.*, 1997). The symptoms of intoxication to terrestrial invertebrates are unique and are typified by initial flaccid paralysis followed by weak tremors and continuous movement of crochets and mandibles (Thompson *et al.*, 1995). The onset of intoxication is rapid with little, if any, recovery.

Although bees (honey bees and bumble bees) are highly sensitive to spinosad via oral and contact exposure routes, studies with honeybees showed no significant mortality following laboratory exposure to alfalfa that was sprayed with a spinosad formulation at 18 g/m^2 and allowed to dry for 3, 8, or 24 hours. The lack of toxicity of dry residues of spinosad to bees suggests that the risk to bees will be negligible if the applications are made when bee activity is low or if bees are allowed to enter such areas only after spray deposits have dried (Dow AgroSciences, 2001). In addition, the program bait formulation contains ammonium acetate, a compound that attracts Medfly but repels honey bees. Field studies in Guatemala have shown that spinosad bait applications cause no adverse effects to honey bees, based upon no mortality and no effect on brood size, pollen reserves, honey panels, and hive weight (Rendon *et al.*, 2000).

Beetles, aphids, spiders, mites, lacewings, minute pirate bugs, and cockroaches are quite tolerant of spinosad and would not be affected by exposures. However, insects that are attracted to a bait are at risk of higher mortality. Previous bait formulations using malathion attracted many species (e.g., midges, gnats, pomace flies, acalypterate muscoid flies, and some soil mites) (Troetschler, 1983), whereas the baits (mazoferm and solulys) used in more recent programs with spinosad formulations are less attractive to nontarget insects. Unlike with malathion bait applications, applications of spinosad bait are not expected to affect local populations of butterflies or moths. Lepidopteran species whose caterpillars consume leaves with spinosad residues or groom vigorously after exposure to

residues, would not be expected to have high mortality because of the highly dispersed droplets and low concentrations of the bait formulation. Ground applications of spinosad bait would be expected to expose fewer species than aerial applications and have less adverse effects on terrestrial invertebrates.

Populations of sensitive nontarget invertebrate species in the program area would be expected to experience declines until their populations recover through recolonization from surrounding untreated areas. However, such impacts are limited by the timing of application (morning), frequency (2–11 day interval), and duration of potential program (a few months per year).

Spinosad is slightly to moderately toxic to fish and most aquatic invertebrates, but the expected concentrations of spinosad in the water of aquatic habitats are several orders of magnitude less than any concentrations known to adversely affect aquatic organisms. This provides an advantage over malathion bait applications that have greater potential for effects on nontarget aquatic species. The lack of adverse impact from spinosad bait applications has been confirmed by actual monitoring data from previous programs (USDA, 2000; USDA, 2001a).

D. Site-specific Issues

Preparation for this EA included consideration for unique aspects of the Guatemalan and Mexican environment, but concentrated on Guatemala where most program actions are expected to occur. The physiographic conditions within the program area are very diverse. Much of central and southern Guatemala is very mountainous with large areas where Medfly hosts are not present. The sparsely populated Department of Peten has thick tropical rainforests with isolated villages where host plants could occur. The Pacific coastal plain and river valleys are the primary areas in Guatemala where active program actions are expected. Mountainous conditions in southern Mexico and Guatemala divide potential program treatment areas. Major bodies of water and other sensitive physiographic sites occur throughout the potential program areas.

The human population of the program area is very diverse. It is expected that the majority of the people in the eradication zones will speak Spanish. Safety communications will be provided in Spanish and English. In addition, there are substantial numbers of persons who speak one or more of the 21 Mayan languages that were officially recognized by the Academy of Mayan Languages of Guatemala, and by a government decree of November 23, 1987. To the extent possible, program personnel should coordinate with local officials so that appropriate notification of program actions can be provided to the public. Much

of the treatment area is rural and logistics impede notification in many areas. In those circumstances, FM and two-way radio may be the primary means of communication with remote communities. Aerial bait spray applications are not expected to be made directly over incorporated towns and cities, but unincorporated habitations, such as coffee fincas (plantations), in the treatment areas can be expected to receive periodic treatments.

Primarily because of the low concentration of the active ingredient in the formulation, no significant adverse environmental consequences are foreseen for humans, including program workers or the general public. No significant adverse effects are anticipated for nontarget species, including nontarget invertebrates. Humans and other nontarget species are protected from adverse environmental effects by program design, routine safety procedures, and specially established mitigative measures. The results of the risk assessment indicate that spinosad bait spray poses substantially less risk to human health, wildlife, and environmental quality than malathion bait spray used in past programs, so no significant adverse environmental effects are anticipated for the proposed program chemical applications. The placement of bait stations in trees above the reach of people precludes any potential human exposure or adverse human health effects.

Environmental conditions and Medfly host crops (principally coffee), such as those which exist in the proposed treatment area of Guatemala, were considered in the EA's determination of potential environmental effects. Because the same kinds of conditions were considered and because the adverse impacts from program applications are either unchanged (malathion bait spray in Mexico) or diminished (spinosad bait spray), no significant environmental effects are anticipated for humans, the physical environment, or nontarget species as a consequence of the proposed treatments.

The continuing use of malathion bait spray in the program in Mexico does pose higher risks to human health, nontarget species, and environmental quality than the use of spinosad in Guatemala, but neither application method poses any significant risks. If the proposed program reduces the number of infestations in Mexico and an efficacious spinosad bait spray formulation is registered for program use in Mexico, substantial further reductions in potential risk are possible.

Hypersensitive humans experience toxicological symptoms and signs at dosage levels much lower than those that are required to produce the same symptoms in the majority of the population. The hypersensitive individuals constitute only a small portion of the total population. The program is not aware of any listing of hypersensitive individuals located in the program areas of Guatemala or Mexico.

Any persons having this condition and informing the program of personal health concerns will be notified of the times and locations of program treatments in the area. This will provide those individuals with sensitivity to chemical exposure the chance to avoid or minimize potential exposure from program chemical applications.

Mitigative procedures (EA, section VII) (USDA, 1991) for the program include operational procedures that ensure the safe aerial and ground application of pesticide, safe storage and handling of pesticide, and protection of nontarget pollinator species.

No cumulative impacts (those that result from the incremental impact of the program action when added to other past, present, and reasonably foreseeable future actions) are predicted for the proposed treatments. The low residues from pesticide applications and rapid degradation preclude accumulation of insecticide in the environment and limit effects from exposures to acute impacts. Because of the program's combination of integrated control, low pesticide application rates of non-persistent chemicals, routine operational procedures, and mitigative measures, there is no potential for unavoidable environmental impact.

E. Endangered and Threatened Species

For the 1991 EA, APHIS prepared biological assessments of Guatemala species that were U.S. federally listed as endangered or threatened, or U.S. proposed for endangered or threatened status, or that were of special concern to the Government of Guatemala. Those assessments revealed no expected significant adverse environmental effects.

Special consideration was made for the potential use of spinosad bait spray to affect endangered, threatened, proposed, and special-concern wildlife and plants. A review of these species found that no adverse effects are anticipated from the application of spinosad bait spray by the program.

Because the potential risks to wildlife and plants by the proposed program are either unchanged (malathion bait spray) or substantially reduced (spinosad bait spray) from those analyzed in the 1991 EA, no adverse effects are anticipated for the endangered, threatened, and proposed species as a consequence of the proposed treatments.

IV. Agencies, Organizations, and Individuals Consulted

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Record of Decision
Spinosad for the Moscamed Program
Environmental Analysis
December 2001

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has prepared an environmental analysis (EA) that analyzes the addition of spinosad bait, a new control method, to the Guatemala Moscamed Program. This EA, the previous EA's for this program, and a comprehensive environmental impact statement, "Fruit Fly Cooperative Control Program Final Environmental Impact Statement – 2001" (EIS) have provided comprehensive analysis of aspects of the program and of its technology, are incorporated by reference in this document, and are available from:

U.S. Department of Agriculture
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For this program, APHIS previously analyzed a range of alternatives, all of which (including no action) were determined to have potential environmental consequences. For the program, APHIS employs integrated control because of its capacity to reduce the overall magnitude of potential environmental consequences. The integrated control strategy of the Moscamed Program uses singly or in combination any of the following component control methods: sterile insect technique (SIT), chemical control, cultural control, and regulatory control.

This EA analyzed the potential environmental consequences of the addition of spinosad bait to the array of chemical control methods available to the program. Spinosad has been shown to be effective for Medfly control, it is efficacious at low application rates, it is non-persistent in the environment, and it has been shown to have substantially lower impact on nontarget species (including honeybees) than other chemicals used for the same purpose.

Following review of endangered and threatened species, and their critical habitats, in the program area of operations, APHIS has determined that this program will have no adverse impacts to those species or their critical habitats.

I find that implementation of the proposed program will not significantly impact the quality of the human environment. I have considered and based my finding on the quantitative and qualitative risk assessments of the proposed pesticides and on my review of the program's operational characteristics. In addition, I find that there will be no disproportionate adverse effects to minority or low income populations from program actions, and that the environmental process undertaken for this program is entirely consistent with the principles of "Environmental Justice," as expressed in Executive Order No. 12898. Lastly, based on my review of the associated environmental analyses (the site-specific analyses for Guatemala and APHIS' programmatic EIS for cooperative fruit fly control), I have not found evidence of significant environmental impact associated with this proposed program, and I have determined that another environmental impact statement does not need to be prepared and that the program may proceed.

/s/ December 24, 2001

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Date